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EXAMINER

COLEMAN, BRENDA LIBBY

ART UNIT	PAPER NUMBER
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1624

DATE MAILED: 02/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/068,711	Applicant(s) KEES ET AL.	
	Examiner Brenda L. Coleman	Art Unit 1624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-59 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-59 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/29/02</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Claims 1-59 are pending in the application.

Priority

1. This application filed under former 37 CFR 1.60 lacks the necessary reference to the prior application. A statement reading "This is a continuation-in-part of copending application 09/291,558, filed on April 14, 1999, **now abandoned**, which claims the benefit of U.S. Provisional Application No. 60/081,662 filed April 14, 1998, the entire disclosure of which is hereby incorporated by reference." should be entered following the title of the invention or as the first sentence of the specification. Also, **the current status of all nonprovisional parent applications referenced should be included.**

Information Disclosure Statement

2. The information disclosure statement filed March 29, 2002 contains three foreign patent documents, which are not clear as to the exact nature of their presence. The following references are directed to subject matter which has no apparent bearing on this application, i.e. EP 0 307 156 is Breech Locking System for Self Loading Firearms; WO 98/00480 is Liquid Fuel Generating Coloured Flame for Candle; and EP 0 307 157 is Low Stress Encapsulant Compositions.

Clarification is hereby requested with respect to these references.

Specification

3. The disclosure is objected to because of the following informalities:

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a) The preferred embodiments of G on page 5, line 16 includes several moieties, which are not disclosed in the genus represented by the variable G, i.e. pyridyl-urea and benzyl-urea.

b) The preferred embodiments of "R9" on page 5, lines 20-25 are unclear since there is no variable R9 in formula I.

c) Table 1 on page 43 contains a formula with the variable R_9 and the Table contains the variable R9, neither of which correspond to formula I where the variable is R^9 . See also Table 2 on page 45; Table 3 on page 48; Table 4 on page 51; Table 5 on page 54; Table 6 on page 59; Table 7 on page 61; Table 8 on page 64; Table 9 on page 67; Table 10 on page 71, Table 11 on page 74, Table 12 on page 78, and Table 13 on page 85, etc.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 44-48 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The scope of the method claims are not adequately enabled solely based on its inhibitory effect on the

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integrin receptor provided in the specification. The specification, while being enabling for metastasis, angiogenesis, restenosis, bone resorption, etc., does not reasonably provide enablement for treatment of all disorders claimed herein.

Recent studies on experimental and clinical pharmacology of integrin receptors cited in Annual Reports in Medicinal Chemistry indicate that the following disorders are associated with integrin receptor $\alpha_v\beta_3$: metastasis, angiogenesis, tumor growth, inflammation, restenosis, bone resorption and adenovirus. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims. In addition to other disorders, which are difficult to treat these claims call for the treatment of cancer, which are capable of being modulated by inhibiting an activity of integrin receptor. However, there never has been a compound capable of treating cancer generally. There are compounds that treat a range of cancers, but no one has ever been able to figure out how to get a compound to treat cancer generally, or even a majority of cancers. Thus, the existence of such a "silver bullet" is contrary to our present understanding in oncology. Even the most broadly effective antitumor agents are only effective against a small fraction of the vast number of different cancers known. This is true in part because cancers arise from a wide variety of sources, such as viruses (e.g. EBV, HHV-8, and HTLV-1), exposure to chemicals such as tobacco tars, genetic disorders, ionizing radiation, and a wide variety of failures of the bodies cell growth regulatory mechanisms. Different types of cancers affect different organs and have different methods of growth and harm to the body, and

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different vulnerabilities. Thus, it is beyond the skill of oncologists today to get an agent to be effective against cancers generally, evidence that the level of skill in this art is low relative to the difficulty of such a task.

5. Claims 44-59 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. It is the Wands factors, which are used to evaluate the enablement question. In re Wands, 8 USPQ2d 1400 (Fed. Cir. 1988); Ex parte Forman, 230 USPQ 546. The factors include: 1) The nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the breadth of the claims, and 7) the quantity of experimentation needed.

The nature of the invention in the instant case, has claims which embrace acylresorcinol compounds. The scope of "prodrug" is not adequately enabled. Applicants provide no guidance as how the compounds are made more active in vivo. The choice of a "prodrug" will vary from drug to drug. Therefore, more than minimal routine experimentation would be required to determine which prodrug will be suitable for the instant invention.

The instant compounds of formula (I) wherein the prodrugs are not described in the disclosure in such a way the one of ordinary skill in the art would no how to prepare the various compounds suggested by claims 1-7. In view of

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the lack of direction provided in the specification regarding starting materials, the lack of working examples, and the general unpredictability of chemical reactions, it would take an undue amount of experimentation for one skilled in the art to make the claimed compounds and therefore practice the invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

6. Claims 1-6, 8-20 and 22-59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The following reasons apply:

a) Claim 1 is vague and indefinite in that it is not known what is meant by the definition of R^8 and R^9 , where R^8 and R^9 are the moiety **trichoroalkylalkoxy**.

b) Claims 1-6, 9-10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38 and 43-59 are vague and indefinite in that it is not known what is meant by the definition of R^8 and R^9 , where R^8 and R^9 are the moiety **arakenyl**.

c) Claim 2 recites the limitation "imidazol-2yl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.

d) Claim 2 recites the limitation "5-amino 1,2,4-triazol-3-yl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.

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e) Claim 3 recites the limitation "imidazol-2-yl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.

f) Claim 3 recites the limitation "5 amino 1,2,4-triazol-3-yl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.

g) Claim 8 recites the limitation "imidazol-2-yl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.

h) Claim 8 recites the limitation "5 amino 1,2,4-triazol-3-yl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.

i) Claims 10, 12 and 14 recite the limitation "1,4,5,6-tetrahydropyrimidinyl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.

j) Claim 11 is vague and indefinite in that it is not known what is meant by propoxy in the nomenclature of the third species.

k) Claim 11 is vague and indefinite in that it is not known what is meant by isopropoxy in the nomenclature of the fourth species.

l) Claim 11 is vague and indefinite in that it is not known what is meant by tetrahydropyrimidin in the nomenclature of the fifth, ninth, thirteenth and fourteenth species.

m) Claim 11 is vague and indefinite in that it is not known what is meant by amon in the nomenclature of the eighth species.

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n) Claim 13 is vague and indefinite in that it is not known what is meant by the nomenclature of the first species which is missing a close bracket and an open parenthesis, i.e. {[(butylamino)carbonyl)amino}.

o) Claim 13 is vague and indefinite in that it is not known what is meant by hydroxy in the nomenclature of the third species.

p) Claim 13 is vague and indefinite in that it is not known what is meant by the nomenclature of the ninth species which is missing a close parenthesis, i.e. ({2-hydroxy-4-[2-(1,4,5,6-tetrahydropyrimidin-2-ylamino).....

q) Claim 15 is vague and indefinite in that it is not known what is meant by [2,30dimethylbenzoyl)amino] in the nomenclature of the second from the last species.

r) Claim 16 is vague and indefinite in that it is not known what is meant by the close bracket which appears after the period of the claim.

s) Claim 17 is vague and indefinite in that it is not known what is meant by the nomenclature of the second species which is missing a close } and an open parenthesis, i.e. {[(benzyloxy)carbonyl]amino}.

t) Claim 17 is vague and indefinite in that it is not known what is meant by propanoic acid in the nomenclature of the thirteenth species.

u) Claim 17 is vague and indefinite in that it is not known what is meant by pyrimidin-2-ylamino in the nomenclature of the sixteenth species.

v) Claim 17 is vague and indefinite in that it is not known what is meant by the nomenclature of the last species, which is missing an open parenthesis, i.e. [2-pyrimidin-2-ylamino)ethoxy].

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w) Claim 18 is vague and indefinite in that it is not known what is meant by the moiety NHCONH⁹.

x) Claim 19 is vague and indefinite in that it is not known what is meant by the nomenclature of the second species, which is missing an open parenthesis, i.e. [tert-butylamino)carbonyl].

y) Claim 19 is vague and indefinite in that it is not known what is meant by buytl in the nomenclature of the third species.

z) Claim 19 is vague and indefinite in that it is not known what is meant by pyrimdin-2-ylamino in the nomenclature of the fourth species.

aa) Claim 19 is vague and indefinite in that it is not known what is meant by the nomenclature of the seventh species, which is missing an open parenthesis, i.e. [2-pyrimidin-2-ylamino)ethoxy].

ab) Claim 19 is vague and indefinite in that it is not known what is meant by the nomenclature of the fourteenth species, which is missing an open parenthesis, i.e. [4-trifluoromethyl)anilino].

ac) Claim 19 is vague and indefinite in that it is not known what is meant by the nomenclature of the second from the last species, which is missing a close bracket and an open parenthesis, i.e. ([{2-phenylethyl)amino]carbonyl}amino).

ad) Claim 19 is vague and indefinite in that it is not known what is meant by the nomenclature of the last species, which is missing a close parenthesis, i.e. ({2-hydroxy-4-[2-(pyrimidin-2-ylamino)ethoxy]benxoyl}

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ae) Claims 20, 22 and 24 recite the limitation "4,5-dihydro-1H-imidazol[yl]" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.

af) Claim 23 is vague and indefinite in that it is not known what is meant by the nomenclature of the first species, which is missing a close } and an open parenthesis, i.e. {[(butylamino)carbonyl]amino}.

ag) Claim 23 is vague and indefinite in that it is not known what is meant by the nomenclature of the second from the last species, which is missing an open bracket, i.e. {[(1,1'-biphenyl]2-ylamion)carbonyl]amino}.

ah) Claim 25 is vague and indefinite in that it is not known what is meant by the nomenclature of the thirteenth species, which is missing a close } and an open parenthesis, i.e. {[(E)-3-phenylprop2-enoyl]amino}.

ai) Claim 26 recites the limitation "3,4,5,6-tetrahydro-2H-azepinyl" in the definition of G. There is insufficient antecedent basis for this limitation in the claim.

aj) Claim 27 is vague and indefinite in that it is not known what is meant by the nomenclature of the fourth, eleventh and twelfth species, which is missing a close parenthesis, i.e. ({2-hydroxy-4-[2-(3,4,5,6-tetrahydro-2H-azepin-7-ylamino)ethoxy]benzoyl}amino).

ak) Claim 29 is vague and indefinite in that it is not known what is meant by the nomenclature of the seventh species, which is missing a close parenthesis, i.e. {[4-(2- {[amino(imino)methyl]amino}ethoxy-2-hydroxybenzoyl]amino}.

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al) Claim 29 is vague and indefinite in that it is not known what is meant by the nomenclature of the eighth species, which is missing a close }, i.e. {[(butoxycarbonyl)amino].

am) Claim 29 is vague and indefinite in that it is not known what is meant by the nomenclature of the ninth species, which is missing a close bracket, i.e. {4-(2-{[amino(imino)methyl]amino}ethoxy)-2-hydroxybenzoyl]amino}.

an) Claim 29 is vague and indefinite in that it is not known what is meant by the nomenclature of the twelfth species, which is missing a close parenthesis and an open }, i.e. {[(prop-2-ynyloxy)carbonyl]amino}.

ao) Claim 31 is vague and indefinite in that it is not known what is meant by the nomenclature of the first species, which is missing a close bracket, a close parenthesis and a close }, i.e. {[4-(2-

ap) Claim 31 is vague and indefinite in that it is not known what is meant by the nomenclature of the second species, which is missing a close parenthesis, i.e. {[20methoxyanilino)carbonyl]amino}.

aq) Claim 33 is vague and indefinite in that it is not known what is meant by the nomenclature of the third species, which is missing a close parenthesis, i.e. {[4-(2-{[amino(imino)methyl]amino}ethoxy)-2-hydroxybenzoyl]amino}.

ar) Claim 33 is vague and indefinite in that it is not known what is meant by the nomenclature of the tenth species, which is missing a close }, i.e. {[4-(2-{[amino(imino)methyl]amino}ethoxy)-2-hydroxybenzoyl]amino}.

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as) Claim 35 is vague and indefinite in that it is not known what is meant by the nomenclature of the first species, which is missing a close parenthesis, i.e. {{{benzyloxycarbonyl]amino}}.

at) Claim 35 is vague and indefinite in that it is not known what is meant by the nomenclature of the second species, which is missing a close parenthesis, i.e. {{{methoxycarbonyl]amino}}.

au) Claim 35 is vague and indefinite in that it is not known what is meant by the nomenclature of the third species, which is missing a close parenthesis, i.e. {{{ethoxycarbonyl]amino}}.

av) Claim 35 is vague and indefinite in that it is not known what is meant by the nomenclature of the fourth species, which is missing a close parenthesis, i.e. {{{propoxycarbonyl]amino}}.

aw) Claim 35 is vague and indefinite in that it is not known what is meant by the nomenclature of the fifth species, which is missing a close parenthesis, i.e. {{{isopropoxycarbonyl]amino}}.

ax) Claim 35 is vague and indefinite in that it is not known what is meant by the nomenclature of the sixth species, which is missing an open parenthesis, i.e. {[benzylamino)carbonyl]amino}.

ay) Claim 37 is vague and indefinite in that it is not known what is meant by the nomenclature of the first species, which is missing an open bracket and a close }, i.e. ({[(pridin-3-ylmethyl)amino]carbonyl]amino)ethoxy]benzoyl]amino).

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az) Claim 37 is vague and indefinite in that it is not known what is meant by the nomenclature of the second, third, fourth, fifth, ninth and thirteenth species, which is missing a close parenthesis, i.e. ({[pyridin-3-ylmethyl)amino]carbonyl}amino).

ba) Claim 37 is vague and indefinite in that it is not known what is meant by the nomenclature of the seventh species, which is missing a close parenthesis, i.e. 3-({2-hydroxy-4-[2-{{(pyridin-3-ylmethyl)amino]carbonyl}amino)ethoxy]benzoyl}amino).

bb) Claim 37 is vague and indefinite in that it is not known what is meant by amino0 in the nomenclature of the tenth species.

bc) Claim 39 is vague and indefinite in that it is not known what is meant by the nomenclature of the sixth species, which is missing a close bracket, i.e. 4-[2-({[(pyridin-4-ylmethyl)amino]carbonyl}amino)ethoxy.

bd) Claim 39 is vague and indefinite in that it is not known what is meant by ethoxy:benzoyl in the nomenclature of the sixth species.

be) Claim 39 is vague and indefinite in that it is not known what is meant by the nomenclature of the ninth species, which is missing a close } and an open bracket, i.e. 4-{2-({[(pyridin-4-ylmethyl)amino]carbonyl}amino)ethoxy]benzoyl}amino).

bf) Claim 40 is vague and indefinite in that it is not known what is meant by the nomenclature of the fifth species, which is missing a close parenthesis, i.e. [4-trifluoromethoxy)-benzyl].

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bg) Claim 40 is vague and indefinite in that it is not known what is meant by 020hydroxy in the nomenclature of the eighth species.

bh) Claim 41 is vague and indefinite in that it is not known what is meant by propxy in the nomenclature of the ninth species.

bi) Claim 41 is vague and indefinite in that it is not known what is meant by the nomenclature of the ninth species, which is missing a close parenthesis, i.e. [3-(pyrimidin-2ylamino)-propxy]].

bj) Claim 41 is vague and indefinite in that it is not known what is meant by benzenesulfonyamino in the nomenclature of the last species.

bk) Claim 42 is vague and indefinite in that it is not known what is meant by the nomenclature of the third species, which is missing a close bracket, i.e. 3-[2-hydroxy-4-[2-(3,4,5,6-tetrahydropyrimidin-2ylamino)ethoxy]benzoyl]amino].

bl) Claim 42 is vague and indefinite in that it is not known what is meant by the nomenclature of the second from the last species, which is missing a close bracket, i.e. 3-[2-hydroxy-4-(2-methylpyrimidin-2ylamino)ethoxy]benzoylamino].

bm) Claim 42 is vague and indefinite in that it is not known what is meant by 2-methylpyrimidin-2-ylamino in the nomenclature of the second from the last species.

bn) Claim 45 recites the limitation "the integrin receptor" in the claim. There is insufficient antecedent basis for this limitation in the claim.

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bo) Claims 46 and 47 recite the limitation "cancer" in the claim. There is insufficient antecedent basis for this limitation in the claim.

bp) Claims 56 and 57 recite the limitation "viral infection" in the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-59 are rejected under 35 U.S.C. 102(b) as being anticipated by KEES et al., WO 99/52879. KEES teaches the compounds, compositions and method of use of the instant invention where R⁸ and R⁹ is other than trichloroalkylalkoxy, trifluoromethoxyphenyl and aralkenyl of 7 to 10 carbon atoms.

It is recognized benefit of U.S. Serial Number 09/291,558 filed April 14, 1999 as well as provisional applications 60/081,662 filed April 14, 1998 is being urged. However, the applicant's priority document does not describe the invention of this application serial number 10/068,711. Note for benefit under 35 USC 120 and 35 USC 119, there must be clear support (description and enablement) for claims instantly rejected herein as was set forth in In re Scheiber 199 USPQ 782; In re Lukach, 169 USPQ 795; In re Gostelli, 10 USPQ 2nd 1614;

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Kawai v. Metlesics 178 USPQ 159. Applicants' attention is drawn to the definition of R⁸ and R⁹.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

8. Claims 1-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over KEES et al., WO 99/52879. The generic structure of WO 99/52879 encompasses the instantly claimed compounds (see Formula I on page 3) and for the same use as claimed herein. The examples differ only in the nature of the R¹, R², R³, R⁴, R⁵, G and n substituents. Page 4, line 1 through page 5, line 12 defines the substituent G is one of the moieties spanning lines 5-8; R¹ and R² are independently, hydrogen, alkyl of 1 to 6 carbon atoms, mono or bicyclic aralkyl of 6 to 10 carbon atoms, or heterocycloalkyl-alkyl comprised of a 5 to 10 membered mono or bicyclic heterocycloalkyl having 1 to 3 heteroatoms selected from S, N and O and an alkyl of 1 to 6 carbon atoms; R³ is hydrogen, mono or bicyclic aryl of 6 to 10 carbon atoms, 5 to 10 membered mono or bicyclic heterocycloalkyl having 1 to 3 heteroatoms selected from S, N and O; R⁴ is hydrogen, NHR⁹, OR⁹, NHCO₂R⁹, NHCONHR⁹, NHCOR⁹ or NHSO₂R⁹, provided that R³ and R⁴; R⁵ is hydrogen or alkyl of 1 to 6 carbon atoms; and n as an integer from 1 to 4.

Compounds of the instant invention are generically embraced by WO 99/52879

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in view of the interchange ability of the R^1 , R^2 , R^3 , R^4 , R^5 , G and n substituents of the acylresorcinol ring system. Thus, one of ordinary skill in the art at the time the invention was made would have been motivated to select for example G is imidazolidinyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

9. Claims 1-59 are rejected under 35 U.S.C. 103(a) as being unpatentable over HARTMAN et al., WO 95/32710. The generic structure of WO 95/32710 encompasses the instantly claimed compounds (see Formula on page 17) and for the same use as claimed herein. The examples differ only in the nature of the X, Y, Z, Aryl, A and B substituents. Page 17, line 32 through page 22, line 19 defines the substituent Aryl is a 6-membered aromatic ring containing 0, 1, 2 or 3 N atoms and either unsubstituted or substituted with one or more groups chosen from R^1 and R^2 ; X is selected from ... $-C(=NR^2)-NHR^4$, $-NR^1-C(=NR^2)-NR^3R^4$, or a 4- to 10-membered mono- or polycyclic aromatic or nonaromatic ring system containing 0, 1, 2, 3 or 4 heteroatoms selected from N, O and S and either unsubstituted or substituted with R^{13} , R^{14} , R^{15} or R^{16} ; Y is C_{0-8} alkylene-O C_{0-8} alkylene, C_{0-8} alkylene- NR^1 - C_{0-8} alkylene, ...; Z is $(CH_2)_mO(CH_2)_n$; A is $(CH_2)_mC(=O)NR^3(CH_2)_n$; and B is $-C(R^6)(R^7)-C(=O)R^{12}$. Compounds of the instant invention are generically embraced by WO 95/32710 in view of the interchange ability of the X, Y, Z, Aryl, A and B substituents of the acylresorcinol ring system. Thus, one of ordinary skill in the art at the time the invention was


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made would have been motivated to select for example X is imidazolidinyl as well as other possibilities from the generically disclosed alternatives of the reference and in so doing obtain the instant compounds in view of the equivalency teachings outlined above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brenda L. Coleman whose telephone number is 571-272-0665. The examiner can normally be reached on 9:30-6:00 Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 571-272-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting -SPE of 1624 at 571-272-0661.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Brenda Coleman
Primary Examiner Art Unit 1624
February 19, 2004